REMARKS

The Applicants acknowledge the Examiner's comprehensive Office Action with appreciation. Claims 7-12 remain pending in the application. The Office raises prior art rejections under 35 USC § 102 and 35 USC § 103. The Office also raises formalistic objections.

The Office acknowledges the priority claim to French Application FR 03.08712. The Office also states that the certified copy of the French priority application was filed in International Application No. PCT/FR04/01868, indicating that the certified copy of the priority application was forwarded to the USPTO from the International Bureau in this US National Phase application. The Applicants respectfully submit that a certified copy of the priority application and a certified English translation thereof were filed with the filing papers of the instant application. The Office acknowledged this filing on the "Notice of Acceptance of An Application Under 35 USC 371 and 37 CFR 1.495" mailed on June 9, 2006. Moreover, the priority document as well as the English translation are viewable in the Image File Wrapper (IFW) system at the USPTO website. Thus, the Applicants respectfully request that the Office acknowledge the perfected priority claim as well as receipt of the certified copy of the priority application and certified English translation thereof.

The Office states that the Information Disclosure Statement (IDS) filed with the filing papers of the instant application does not comply with USPTO requirements. The Office states that listed references were not provided by the Applicants and that the IDS has been placed in the application file but the information referred to therein has not been considered. The Applicants note, however, that the instant Office Action includes an Office-acknowledged copy of the Form PTO-1449 which was submitted with the filing papers of the instant application wherein all but one of the listed references appears to have been considered by the Examiner. Thus, the Office appears to have considered the listed references with the exception of the Haguenauer, et al. reference. The Applicants respectfully request confirmation that the references indicated as considered on the Office-acknowledged copy of the Form PTO-1449 have actually been considered by the Examiner. Moreover, the

Applicants also provide a copy of the Haguenauer, et al. reference as well as a new Form PTO-1449 listing this reference.

The Office objects to the format of the instant specification, quoting the preferred Specification form and labeling. The Applicants acknowledge the Office exposition of USPTO patent procedure and will, in the future, strive to conform with this Office preference.

Claim 7 is rejected under 35 USC § 102(a) and 35 USC § 102(e) as being anticipated by Quay (US Published Application No. 2004/0028613, filed on June 25, 2001, published on February 12, 2004). The Applicants respectfully submit that the Quay reference is not available as prior art under 35 USC § 102(a) in view of the instant priority claim to French Application FR 03.08712 (filed on July 17, 2003).

It is the position of the Office that Quay discloses "compositions for mucosal delivery of dopamine receptor agonists." The Office states that Quay specifically discloses piribedil as an example of a dopamine receptor agonist which may be used in the disclosed compositions and that the reference also discloses cyclodextrins (including beta-cyclodextrins) may be used as mucosal-delivery enhancing agents. The Office goes on to state that the reference discloses that various excipients may be used and that the compositions may be in the form of an aqueous solution (e.g., as a nasal spray) or dry powder formulations. Thus, the Office concludes that Quay anticipates each of the elements of the composition recited in Claim 7.

The Applicants respectfully submit that Quay does not explicitly disclose ***a composition*** comprising each and every element of the instantly claimed composition. According to MPEP § 2131.02, if a species is not specifically named and it is necessary to select portions of teachings within a reference and combine them to arrive at a specific composition, anticipation can only be found if the classes of substituents are sufficiently limited or well delineated. Thus, a genus does not necessarily anticipate a claim to a species within the genus. The Applicants further submit that MPEP § 2112 states (referring to Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings, 71 USPQ2d 1081 (CAFC 2004)), that a prior art reference which

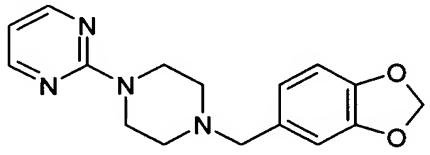
discloses a genus does not inherently disclose all species within that broad category but must be examined to see if a disclosure of the claimed species has been made or whether the prior art reference merely invites further experimentation to find the species.

The Applicants respectfully submit that the only specific composition disclosed in Quay comprises apomorphine as the dopamine agonist. Piribedil is disclosed in a long list of possible dopamine agonists. Similarly, cyclodextrins are disclosed among a long list of possible excipients which may be used in the disclosed compositions. The Office has not demonstrated that one skilled in the art would pick and choose from the various active ingredients and excipients to arrive at the instantly claimed piribedil composition in the form of an aqueous solution or powder. Therefore, the compositions disclosed in Quay do not anticipate the instantly claimed compositions. Reconsideration and withdrawal of the anticipation rejection is respectfully requested.

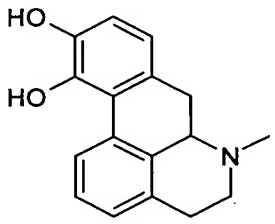
Claims 7-12 are rejected for obviousness under 35 USC § 103(a) based on the disclosure of Merkus (US Patent No. 5,756,483) in view of Deleu, et al. (*Clin. Pharmacokinet.*, **2002**, *41*, 261-309). It is the position of the Office that Merkus discloses pharmaceutical compositions for intranasal administration of apomorphine. The Office states that Merkus discloses that apomorphine is a "very potent dopamine agonist." The Office also states that Merkus discloses apomorphine in the form of a base as well as apomorphine in combination with a cyclodextrin (preferably a methylated β-cyclodextrin with a degree of CH_3-substitution between 0.5 and 3.0, more preferably between 7.1 and 2.1). The Office goes on to state that the reference further discloses that many other excipients may be used and that the compositions may be administered as a nasal spray or powder. The Office acknowledges that Merkus does not disclose piribedil compositions. It is the position of the Office that the ***only*** difference between the composition recited in instant Claims 7-10 and the compositions disclosed in Merkus is that apomorphine has been replaced with piribedil.

The Office states that Deleu, et al. disclose that piribedil and apomorphine are both dopamine agonists which have similar mechanisms of action, similar effects, and similar uses, such as the treatment of Parkinson's disease. The Office also states "Deleu, et al. specifically teach that 'no single best treatment exists for an individual patient with Parkinson's disease. Particularly in the advanced stage of the disease, treatment should be individually tailored'". Based on its interpretation of the Deleu, et al. disclosure, the Office concludes that it would have been obvious to one skilled in the art to modify the compositions disclosed in Merkus by replacing apomorphine with piribedil to arrive at the instantly claimed compositions. With respect to dependent Claims 11-12, it is the position of the Office that, since Merkus discloses apomorphine compositions which overlap the instantly claimed "ranges" and it would have been obvious to one skilled in the art to replace apomorphine with piribedil, Claims 11-12 are also rendered obvious by the combined disclosures of Merkus and Deleu, et al.

The Applicants respectfully submit that piribedil and apomorphine are structurally distinct molecules, as shown below:



Piribedil



Apomorphine

One skilled in the art would recognize that these two substances would possess different pharmacological/pharmacokinetic profiles based on these structural differences. Moreover, as disclosed in the instant specification, the instantly claimed composition provides increased local tolerance and bioavailability for piribedil.

With respect to the Deleu, et al. disclosure, the Applicants respectfully submit that the cited reference itself actually contradicts the Office allegation that this reference teaches the equivalence of apomorphine and piribedil. The passage cited by the

Office, (i.e., "no single best treatment exists for an individual patient with Parkinson's disease. Particularly in the advanced stage of the disease, treatment should be individually tailored") represents nothing more than an invitation to experiment with respect to the use of various substances for the treatment of Parkinson's disease. Moreover, the Deleu, et al. reference also discloses (at page 277) that the dopamine agonists discussed in the reference may be divided structurally into ergoline derivatives, non-ergoline derivatives (including piribedil), and aporphines (including apomorphine). Thus, the Deleu, et al. reference teaches that piribedil and apomorphine are structurally different and that they exhibit different therapeutic effects.

The Applicants respectfully submit that the Office has provided no demonstration that one skilled in the art would have been motivated to employ piribedil in the compositions disclosed in the Merkus reference based on the disclosure of the Deleu, et al. reference to arrive at the instantly claimed compositions. Thus, the instantly claimed compositions are not rendered obvious by the combined disclosure of the cited references. Reconsideration and withdrawal of the obviousness rejection is respectfully requested.

* * * * *

Accordingly, entry and acknowledgment of the IDS, acknowledgement of the perfected claim to priority, reconsideration of all grounds of objection and rejection, withdrawal thereof, and passage of this application to issue are all hereby respectfully solicited.

It should be apparent that the undersigned agent has made an earnest effort to place this application into condition for immediate allowance. If she can be of assistance to the Examiner in the elimination of any possibly-outstanding insignificant impediment to an immediate allowance, the Examiner is respectfully invited to call her at her below-listed number for such purpose.

Allowance is solicited.

Respectfully submitted,

THE FIRM OF HUESCHEN AND SAGE

By: _____

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THE COMMISSIONER IS HEREBY AUTHORIZED TO CHARGE ANY FURTHER OR ADDITIONAL FEES WHICH MAY BE REQUIRED (DUE TO OMISSION, DEFICIENCY, OR OTHERWISE), OR TO CREDIT ANY OVERPAYMENT, TO DEPOSIT ACCOUNT NO. 08,3220.